IVD CE

LACTATE PLUS

Instructions for Use Manual

Laktate

www.laktate.com

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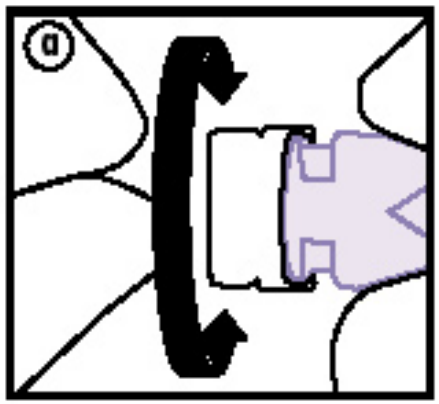
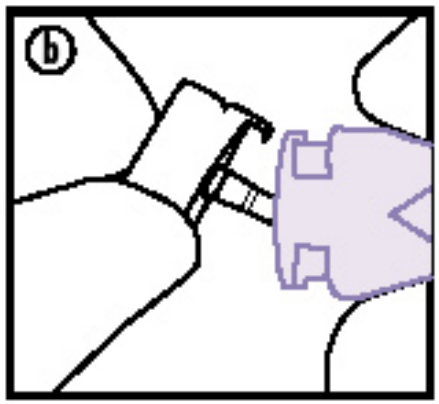
Quick Reference Guide

1. Prepare the lancet.

a. Simply twist off the lancet cap: Hold the lancet body and twist off the lancet cap until you feel it separate from the device.



b. Do not pull, just twist the lancet cap. Dispose of the cap in a suitable container.

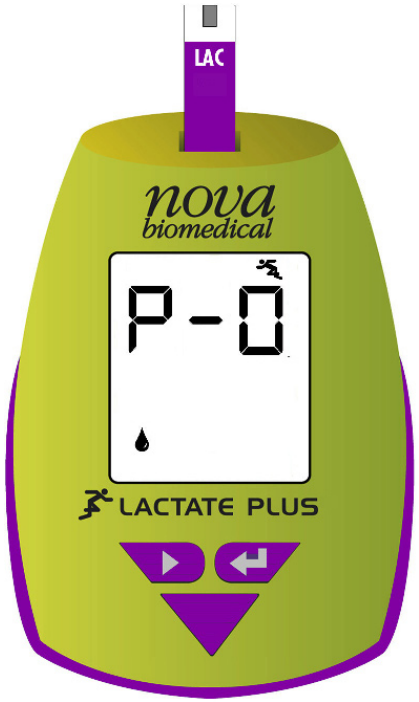


NOTE: *This device is single-use. The needle retracts immediately after sampling. This leaves the device safe for immediate disposal into a sharps container.*

2. Insert a Test Strip.

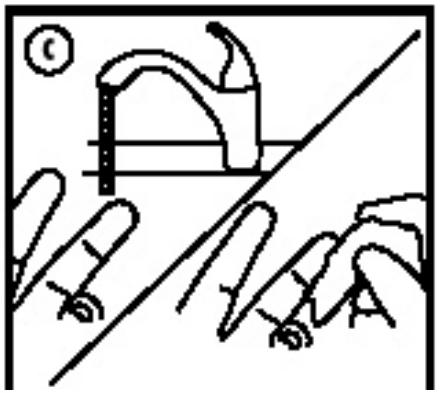
Insert Test Strip: Automatic System Check begins.

User Profile Number displays: use Search key to select profile.

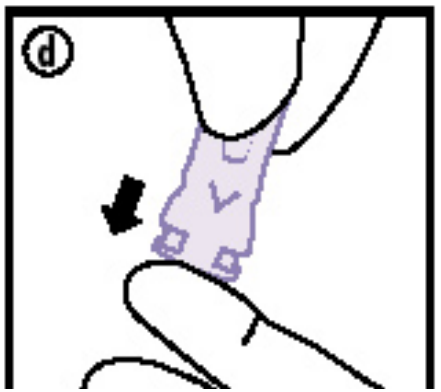


3. Prepare the Puncture Site.

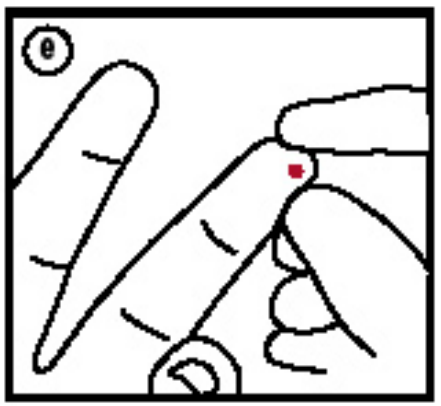
c. The best puncture sites are on the middle or ring finger. Clean the finger tip **thoroughly** with soap and water. Then dry thoroughly.



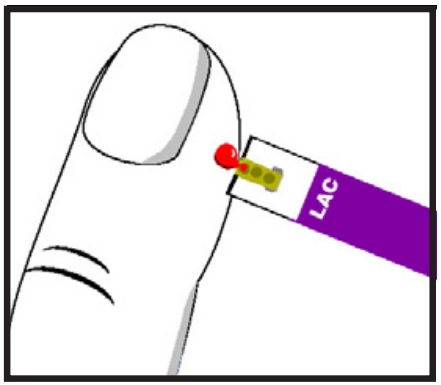
d. Place the auto-Lancet against the pad of the finger, press the release button, remove the device from the finger.



e. Wait a few seconds for a blood drop to form. Wipe off the first drop with a clean tissue. Squeeze the finger to form a second drop of blood. **Do not squeeze vigorously.**



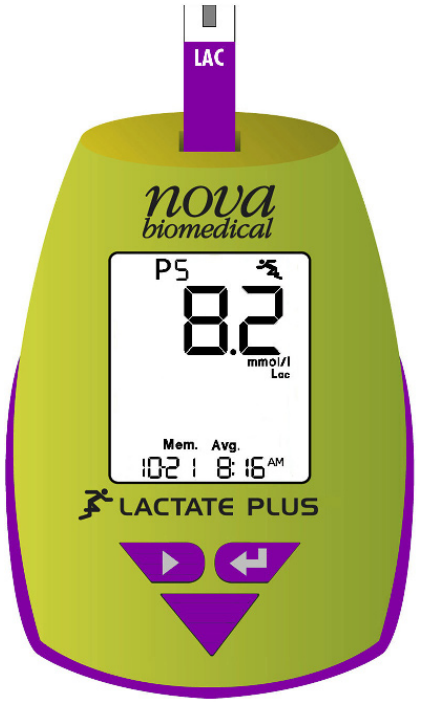
4. Add Blood to Test Strip.



When the second blood drop appears, touch the end of the test strip to the blood drop until the well of test strip is full and the meter beeps.

The on-screen Blood Drop flashes on and off repeatedly until sufficient blood has been added to the test strip.

The Lactate result is available on-screen in 13 seconds.



Nova Biomedical recommends that the user of this device read this manual and accompanying product inserts completely before performing blood measurements.

Intended Use

The Lactate Plus Meter System is intended for use by healthcare professionals to quantitatively measure lactate in whole blood to evaluate physical performance and/or to establish a proper intensity of exercise for athletes. The device system is for *in vitro* diagnostic use only.

Symbols

The following are symbols that are used in this manual, on insert sheets, and on the Lactate Plus Meter.

IVD — *In vitro* diagnostic medical device

REF — Catalog number

CE — Fulfills requirements of Directive 98/79 EC (IVDD)

Temperature limitation

Caution, consult accompanying documents

Upper Limit of Temperature

Consult instructions for use

Manufactured by

Biological risk

Warnings, Cautions, and Notes

NOTES *provide important or helpful operating information.*

CAUTIONS *provide information that is important for instrument protection.*

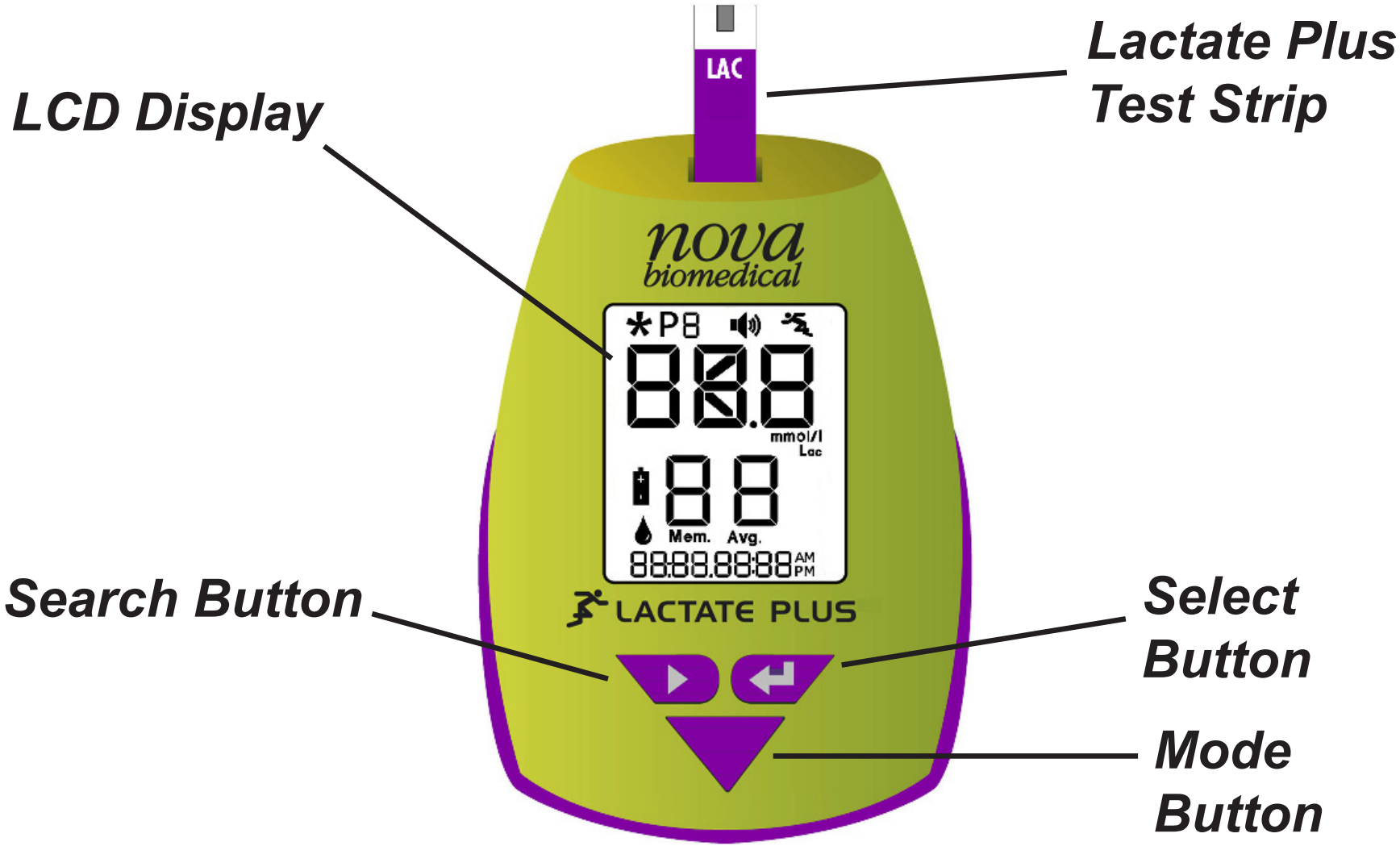
WARNINGS *provide information that is important for user protection or about risk for inaccurate results.*

The Lactate Plus Meter

WARNING: *Blood samples and blood products are potential sources of hepatitis and other infectious agents. Handle all blood products with care. Wear gloves when performing measurements on another person. Items that are used to measure lactate, i.e., test strips, lancets, and alcohol swabs, must be disposed of in accordance to local regulations to avoid risk to anyone.*

WARNING: *Please keep the Lactate Plus Meter and its accessories out of reach of small children to prevent accidents through improper handling and to avoid the risk of small parts being swallowed.*

Introduction



LCD Display

Lactate Plus Test Strip

Search Button

Select Button

Mode Button

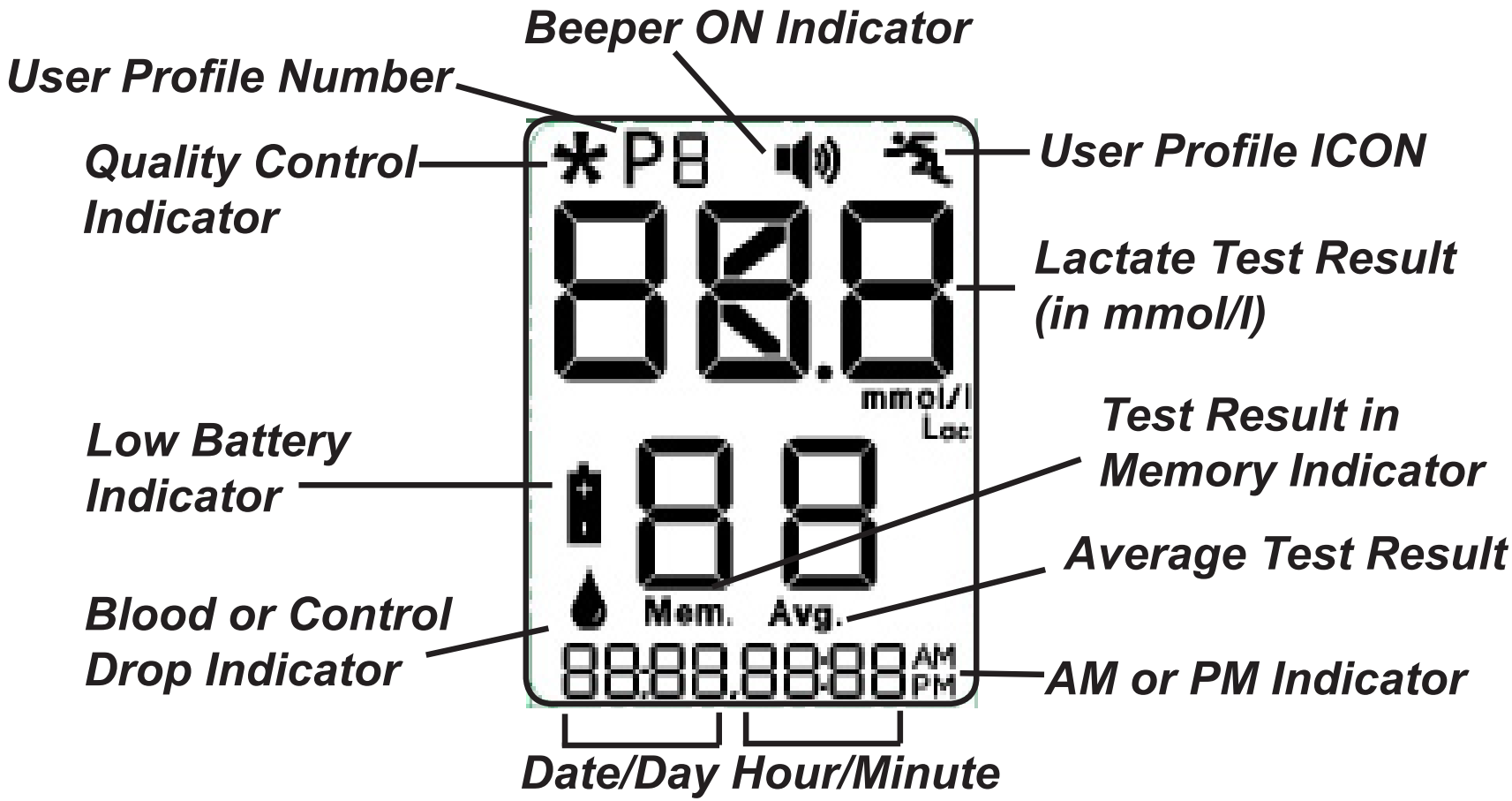
Lactate Plus Meter

Introduction

The Lactate Plus Meter is a hand-held testing device that measures lactate (Lac) in whole blood. The test strip is touched to a drop of blood to initiate the test process.

- A simple one-step process provides a blood lactate result.
- Test result is available in 13 seconds.
- There is memory for one common user's set of test results (20):
  Nine specific users' set of test results (10 each);
  Two sets of Quality Control (QC) results (10 each)
- The unit is powered by a battery that can perform for approximately 600 tests.

Introduction



Lactate Plus Meter Screen

Introduction

CAUTION: *The meter should be handled with care. Dropping, rough handling, etc. may damage the meter. Also, protect the meter from moisture, prolonged direct sunlight, and high temperatures.*

Overview

To perform a test, the operator simply inserts a test strip; places a drop of sample onto the test strip; and obtains a lactate test result in 13 seconds. The test result is automatically stored into the meter's memory. The operator can recall, delete, and review test data resident in the meter, including the average for each control and user profile's results.

Meter, Supplies, Transport Case

The Nova Lactate Plus Meter (40828) comes in a soft carrying case that includes:

1. Lactate Plus Meter with Battery
2. Instructions for Use Manual
3. Quick Reference Guide

See Page 39 for a listing of supplies and accessories.

Environmental

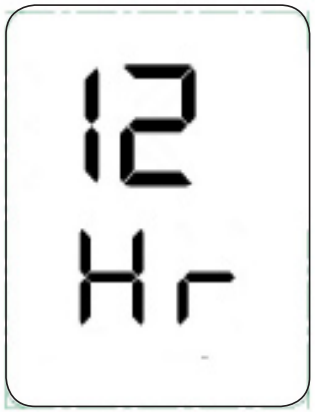
- The storage temperature range for the Meter: -13°F to 115°F (-25°C to 46°C)
- The storage temperature range for the Test Strips and Control Solutions: room temperature - 15°-30°C/59-86°F
- The meter operational temperature range for Lactate: 41°F to 113°F (5°C to 45°C)
- The relative humidity range: 10% to 90% non-condensing

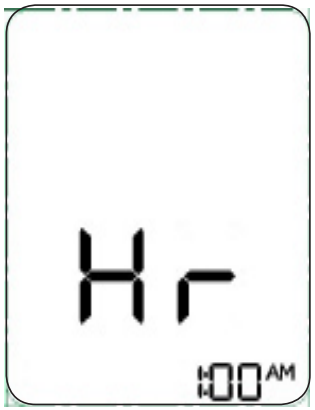
Set the Time

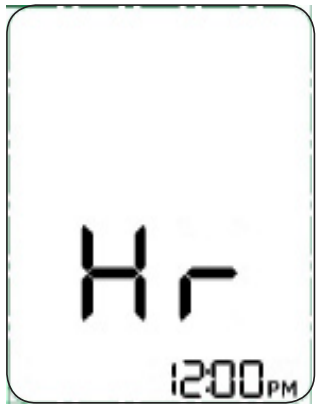
- Press the MODE button for longer than 3 seconds. The meter if in Sleep Mode wakes up and enters the SETUP Mode.
- View the hour (flashing) format: either 12 Hr or 24 Hr by pressing the SEARCH button to toggle between the 2 time format options available.
- Press the SELECT button to choose the Hour Format.
- The meter displays the current time or the default time: 12:00 AM or 0:00 (hours).
- Press the SEARCH button to progress from 1AM to 12PM (for 12 Hr Clock) or 0 to 23 (for 24 Hr Clock). The hour digits will be flashing until selected.

- Press the SELECT button to select the displayed Hour choice.
- Next set the minutes. Press the SEARCH button to progress from 00 to 59 minutes. The minute digits will be flashing until selected.
- Press the SELECT button to select the displayed Minutes choice.

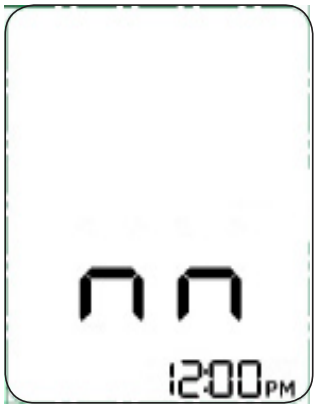
Setup

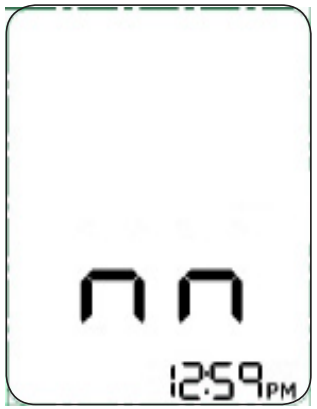




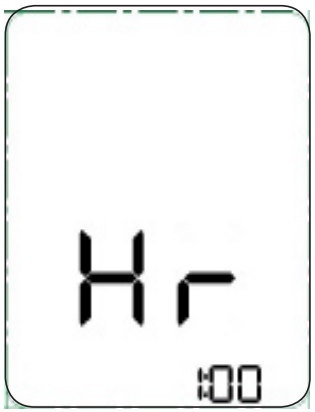


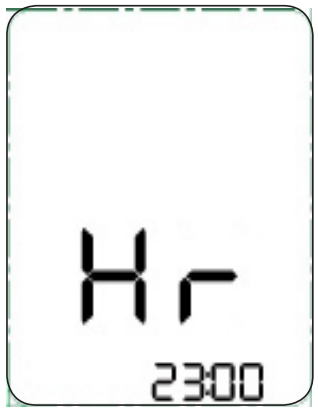
1a. Select 12 Hour, then select hour with AM/PM.



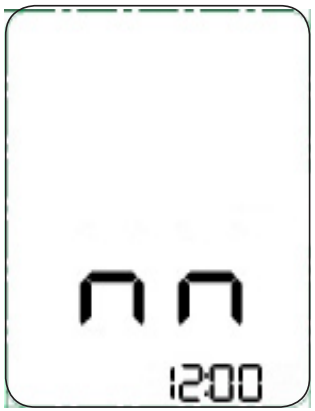


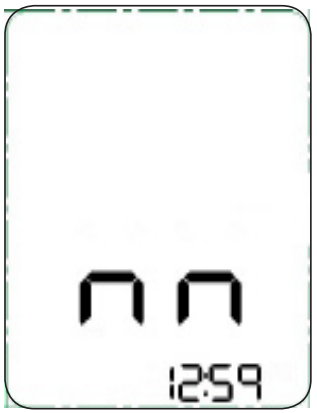
2. Select minutes.





1b. Or Select 24 Hour, then select hour.



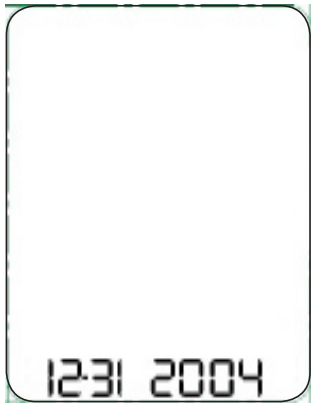


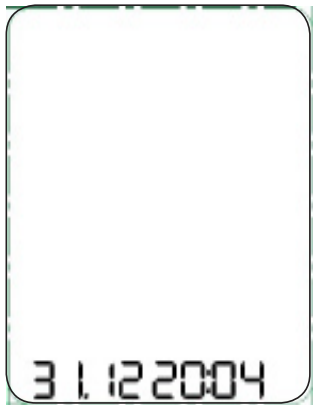
Set Date Format

- After the time has been set up, set date format is next. The display is 12-31 2004 or 31.12 2004.
- You can choose to have the date as DD.MM or MM-DD. These digits will be flashing until selected. Press the SEARCH button to toggle between DD.MM or MM-DD.
- Press the SELECT button to select the displayed Date Format choice.
- Press the SEARCH button to display years from 2004 to 2099. The year numbers will be flashing. Displays current date/time or default (1-01 2004).
- Press the SELECT button to select the displayed Year choice.

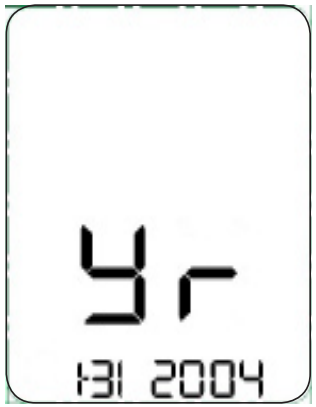
Setup

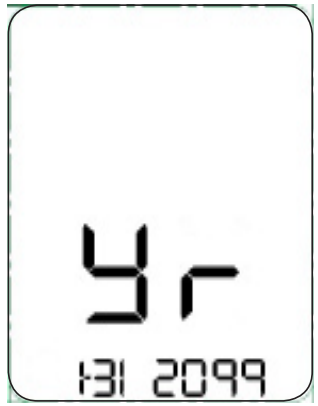
- The date is displayed as selected in the date format: either DD.MM or MM-DD.
- Press the SEARCH button to progress through the 12 months (1 to 12). The 2 month numbers will be flashing.
- Press the SELECT button to select the displayed Month choice.
- Lastly, press the SEARCH button to progress through the days of a month: 1 to 31. The 2 day numbers will be flashing.
- Press the SELECT button to select the displayed Day choice.



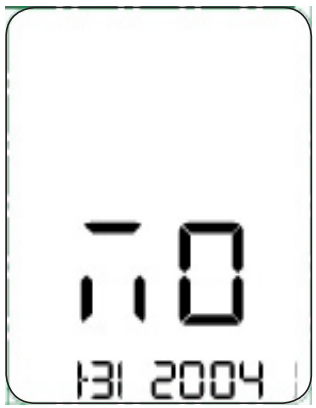


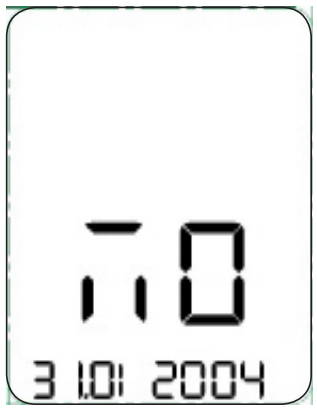
3. Select Date format: MM-DD or DD.MM.



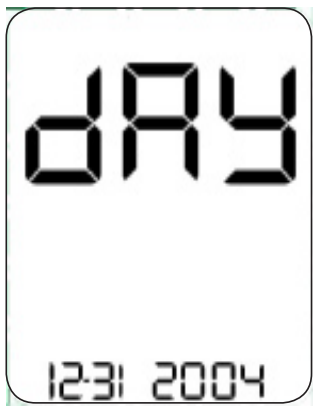


4. Select Year with Search button.





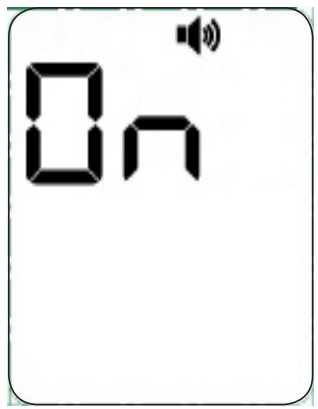
5. Select Month.

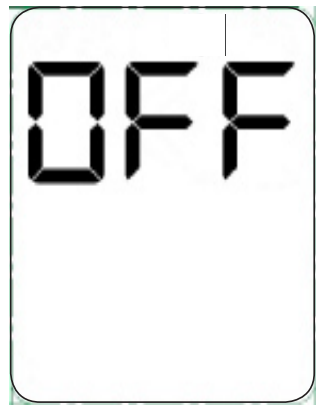


6. Select Day.

Beeper On or Off

- Next is the Beeper on or off. Press the SEARCH button to toggle between ON and OFF (flashing).
- Press the SELECT button to select the displayed ON or OFF choice.

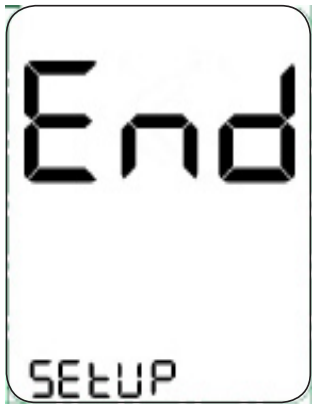




7. Select Beeper ON or Beeper OFF.

End of Setup

- The screen displays END.
- Press the MODE button for 1.5 seconds to save the setup configuration.
- The meter will power down. The new settings will be applied once the meter is powered back up.



8. End of Setup

Testing: Blood and Quality Control Solutions

NOTE: *Before running a blood or quality control test, check that the expiration date of the test strips and control solution has not elapsed. (See product insert sheets for details.)*

The control solution test results should fall within the range of results printed on the label of the control solution. You should run a control solution test:

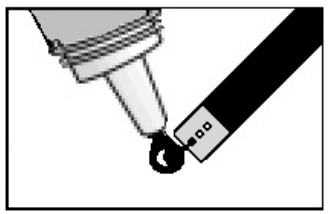
- Before using your Nova Lactate Plus Meter for the first time and at least once a week thereafter
- Each time you open a new box of Nova Lactate Test Strips
- If you leave the Nova Lactate Test Strip vial cap open for an extended period of time
- If you drop your Nova Lactate Plus Meter
- If your results are higher or lower than expected

User should follow the appropriate Federal, State, and Local Guide Lines concerning the running of external quality controls.

Testing: Blood and Quality Control Solutions

Testing a Quality Control Solution

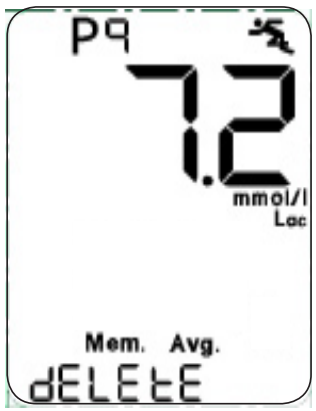
1. Grasp a test strip with logo side up and gold side down. Then insert the gold end into the meter. (See Meter figure.)
2. Identify the sample as a control; use the SEARCH button to find the desired control level: CrL 1 or CrL 2.
3. Shake the control solution well before each use. Discard the first drop.
4. Place a drop of control solution from the bottle at the end of the test strip until the solution is drawn into the well of the test strip.

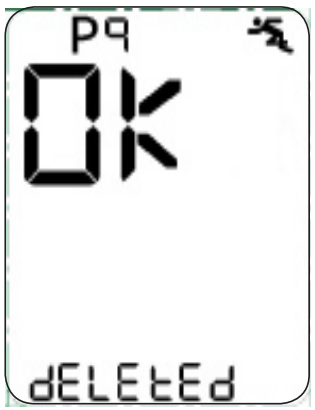


NOTE: *The on-screen Control Drop flashes on and off repeatedly until sufficient control solution has been added to the test strip.*

Testing: Blood and Quality Control Solutions

5. A Lactate quality control test result is available on-screen in 13 seconds.
6. The result is automatically stored into memory.
7. If this result is not needed, press the SELECT button for 2 seconds to go to dELEtE (flashes) mode (while the test strip is still in place).
8. Press SELECT again to confirm deletion or press SEARCH to stop deletion and exit the delete mode.





Testing: Blood and Quality Control Solutions

Testing a Blood Sample

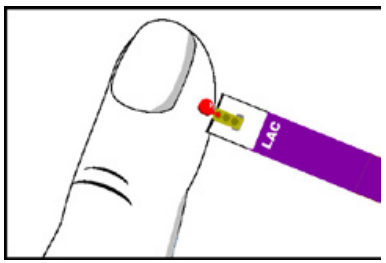
NOTE: *The hands should be warm and relaxed. Obtain blood sample from a finger.*

1. Check that the expiration date of the test strips has not elapsed.
2. Wash hands with water then dry thoroughly. Alternatively, use alcohol pads to clean area 3 times; dry thoroughly after each cleaning.
3. Grasp a test strip. Insert the gold end into the meter.
4. Select a profile number; use the SEARCH button to find the Profile Number (P0 to P9).

NOTE: *Cleaning of the puncture site is important. Sweat left on the fingers may cause falsely high lactate test results.*

Testing: Blood and Quality Control Solutions

5. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.
6. Use the lancet to puncture the finger.
7. Wipe off the first drop with a clean tissue. The first drop may be contaminated.
8. Squeeze the finger to form a second drop of blood. To avoid collection of interstitial fluid as well as blood, **do not squeeze vigorously**
9. When the second blood drop appears, touch the end of the test strip to the blood drop until the well of test strip is full and the meter beeps.



NOTE: *The on-screen Blood Drop flashes on and off repeatedly until sufficient blood has been added to the test strip.*

Testing: Blood and Quality Control Solutions

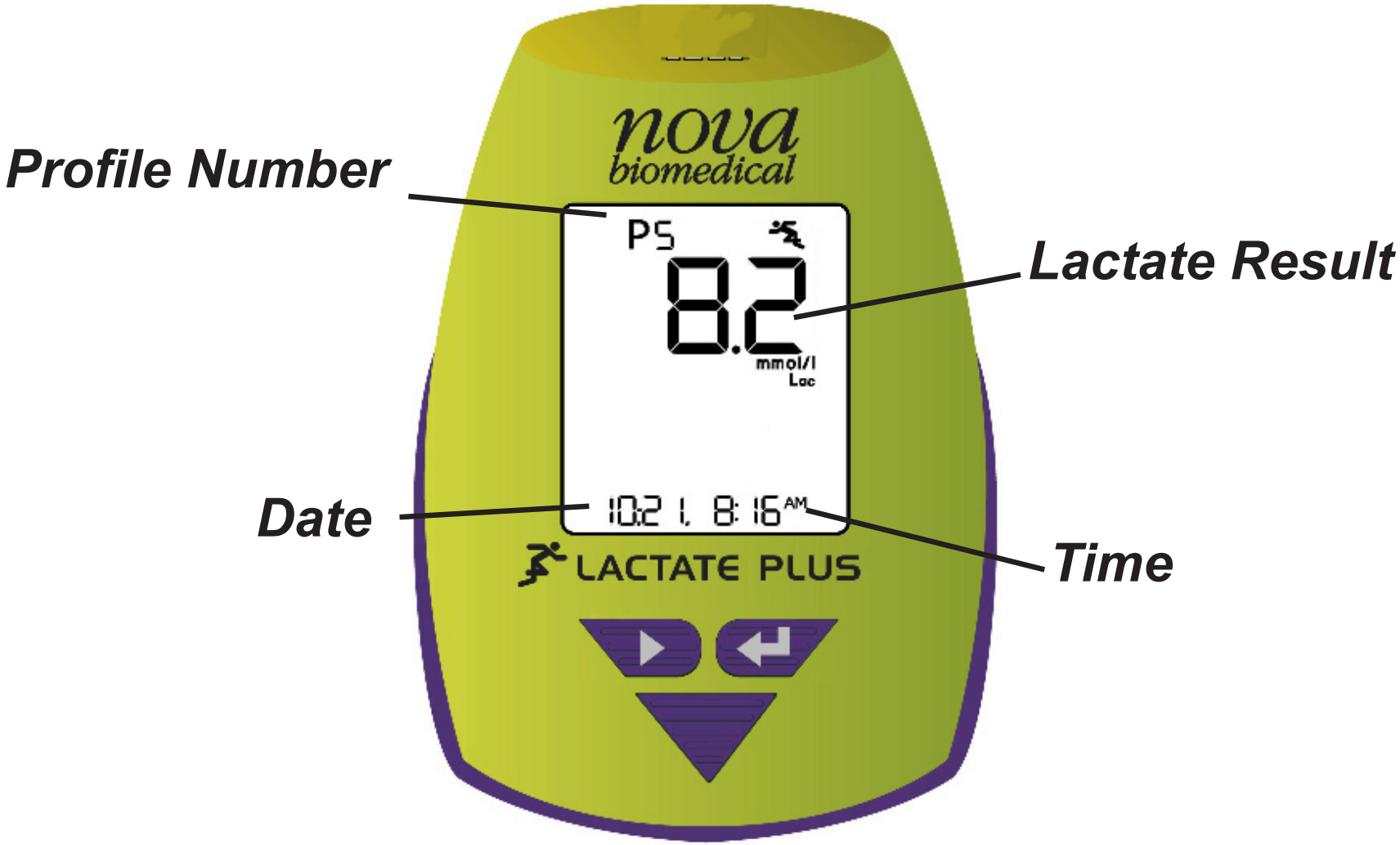
10. If subject has to immediately return to exercise and puncture site is still bleeding, apply light pressure with a cotton pad or tissue until the bleeding stops or cover with a bandage.
11. The Lactate result is available on-screen in 13 seconds.
12. The result is automatically stored into memory.
13. If the result is not needed, press the SELECT button for 2 seconds to go to dELEtE (flashes) mode (while the test strip is still in place).
14. Press SELECT again to confirm deletion or press SEARCH to stop deletion and exit the delete mode.

Testing: Blood and Quality Control Solutions

WARNING: Once a disposable item, i.e., lancet, test strip, alcohol swab, etc., has been used, it is considered contaminated. Dispose of all contaminated materials in accordance with local regulations. Equipment such as lancets and tissues must be used only once and then disposed of even when repeated measurements are being made on the same subject.

Reference
Graeme Maw, Simon Locke, David Cowley, and Patricia Witt. 2000. Blood Sampling and Sampling Techniques. In *Physiological Tests for Elite Athletes.* ed. Christopher John Gore, PhD. 91-92. Champaign, IL. Human Kinetics.

Testing: Blood and Quality Control Solutions



Lactate Plus Meter with Display Results

Data Review

NOTE: *If a test strip is inserted while in the Data Review mode, the meter immediately switches to test mode. If you then exit the test mode, the meter screen goes blank- the meter does not return to the Data Review mode.*

Manually Reviewing Stored Test or Control Results

1. With the meter off, press the MODE button for 2 seconds. (To turn the meter off, press the MODE button for 1.5 seconds.)
2. The most recent test result in the last user's profile is displayed.
3. Use the SEARCH button to scroll back through the user's test results.

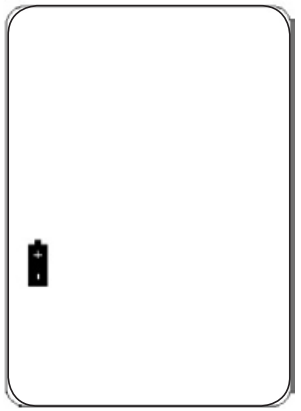
4. Press the MODE button to advance to the user profile (P0 to P9) or control level (*1 or *2) that you want to review.
5. Press the SEARCH button to review the test results for the selected user or the control level.

Basic Upkeep

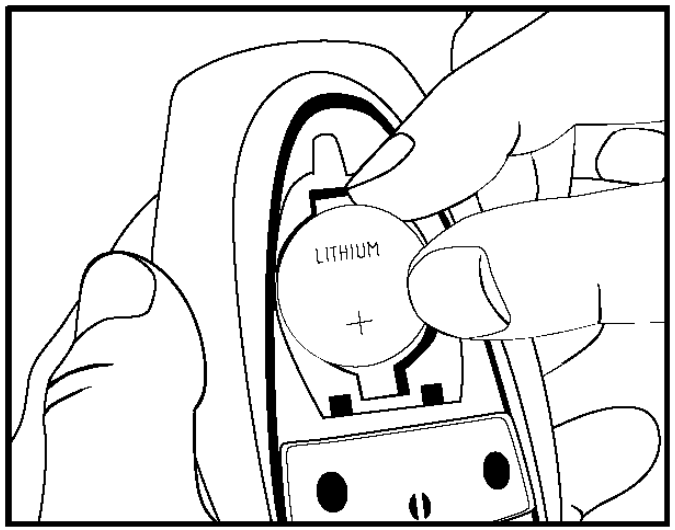
Battery Replacement

The meter is powered by a single 3V coin cell battery, 2450. Replace the battery as follows:

1. Remove the back battery cover on the meter.
2. Remove the battery and replace with a new one with the **+** side facing up.
3. Replace the battery cover.
4. Go to set up, and reset the time and date.



Low Battery



Replacing Battery

Cleaning and Care

If necessary, clean the Lactate Plus Meter with a clean cloth dampened with water. Keep liquids from entering the test strip port or the Search, Enter, and Mode buttons.

CAUTION: *Do Not attempt to open the Lactate Plus Meter to make any repairs. Your warranty and all claims will be void! Only Nova Biomedical authorized service personnel can repair the meter. Call Nova Biomedical or an authorized dealer if the meter needs to be repaired or checked.*

Error Messages

Codes

Code	Alerts	Action
E-0	Software error detected	Perform the test again. If you get the same error, call Nova Technical Support.
E-1	Hardware error detected	Perform the test again. If you get the same error, call Nova Technical Support.
E-2	Meter temperature is outside of the range for testing	Move the meter to an area where the temperature is acceptable (41°-113°F), allow meter to adjust to the temperature. Repeat testing.
E-3	Defective or previously used test strip is detected	Repeat test with a new test strip.
E-4	A short sample (control solution or blood) is identified	Repeat test with a new test strip and adequate sample.
LO or HI	If test results are outside of the measuring range of the meter	Repeat test. If you get the same result, consult your physician.
	Battery level is low	Replace the battery

Appendix

Specifications

Tests Measured	Blood Lactate
Lactate Methodology	Lactate oxidase biosensor
Lactate Test Results	mmol/l (Plasma values)
Sample Type	Whole blood
Lactate Test Range	0.3 to 25.0 mmol/l
Test Time	13 seconds
Test Strip Volumes	0.6 µl
Battery Life (nominal)	600 Tests
Data Output Port	Serial
Data Output Cable (optional)	

Appendix

Operating Ranges:

Temperature Lactate	41° to 113°F (5° to 45°C)
Humidity	10% to 90% relative humidity
Weight	2.65 oz (75 g)
Size	3.6x2.3x0.9 in (91.4x58.4x22.9 mm)

On-board data storage files:

- 1 common file for 20 tests
- 9 additional user files for 10 tests each
- 2 control files, 10 tests each

Appendix

Accessories:

Vial of Test Strips (25) (REF 40813)

Lactate Plus Control Solution, Level 1 (REF 40815)

Lactate Plus Control Solution, Level 2 (REF 40814)

PC Data Communication (upload) Cable (REF 41235)

Soft Carrying Case (41266)

Battery (DL2450) (REF 41221)

Performance Characteristics

The test result range for Nova Lactate Plus Meter is 0.3 to 25.0 mmol/l for Lactate.

Appendix

Accuracy

Accuracy of the Lactate Plus Meter system was assayed at clinical sites by comparing lactate results obtained by Lactate Plus Meter vs YSI Reference method from subjects at clinical sites. Blood lactate measurements obtained from Nova Lactate Plus Meter were compared with the same subjects' results from the YSI, a laboratory reference method. The latter results were plasma-derived values from a blood sample measured on a YSI 2300 Stat Plus Analyzer.

- Number of Samples: 210
- Slope: 0.968
- Correlation Coefficient (r): 0.997
- y-intercept: 0.165 mmol/l
- Range tested: 0.5 - 12.4 mmol/l

These results indicate that Nova Lactate Plus Meter compared well with the laboratory reference method.

Appendix

Precision

Precision of Nova Lactate Plus Meter was measured with both venous blood samples and control solution in laboratory. The results are shown below:

Lactate Level					
	1	2	3	4	5
Lactate Mean (mmol/l) 20 measurements	1.6	6.5	10.8	18.1	22.1
CV%	3.6	1.9	1.6	2.7	3.2
S.D. (mmol/l)	0.06	0.12	0.17	0.49	0.7

Appendix

References

1. Clark, L.C. Jr, Noyes, L.K., Grooms, T.A., Moore, M.S.1984. *Rapid Micromeasurement of Lactate in Whole Blood: Critical Care Medicine*. Vol. 12 pp 481-464.
2. Hirano, K., Yamato, N., Kunimoto, K., and Ohwa, M. 2001. *Novel Electron Transfer mediators Based on Dichloroindophenol Derivatives for Lactate Oxidase: Journal Electroanalytical Chemistry.* Vol. 510 pp 149-152.
3. Shimoje, N., Naka, K., Uenoyama, H., Hamamoto, K., Yoshioka, K., and Kiyoshi, O. 1993. *Electrochemical Assay System with Single-use Electrode Strip for Measuring Lactate in Whole Blood: Clinical Chemistry. Vol.* 39 pp 2312-2314.
4. Sprules, S.D., Hart, J.P., Wring, S.A., and Pittson, R. 1995. *A Reagentless, Disposable, Biosensor for Lactic Acid based on a Screen-printed Carbon Electrode Containing Meldola's Blue and Coated with Lactate Dehydrogenase, NAD+ and Cellulose Acetate: Anal. Chim. Acta.* Vol 304 pp 17-24.

Appendix

Instructional Notes

1. Inserting a test strip overrides all other modes.
2. There is no “All segments Screen” in Upload mode.
3. When in Upload mode, no other meter functions are available, and there is no response by meter to button presses.
4. The meter times out in 5 minutes in Upload mode.
5. Inserting a test strip overrides any mode except Upload mode.
6. If in setup mode when the test strip is inserted, the meter saves all values entered up to that point and immediately switches to test mode. Upon exiting test mode the meter screen goes blank and does not return to setup mode.

7. If in Data Review mode when the test strip is inserted, the meter immediately switches to test mode. Upon exiting test mode the meter screen goes blank and does not return to Data Review mode.
8. Battery low icon is displayed in every mode except setup.
9. Once battery level goes below the threshold that triggers the “low battery” warning, it continues to give the warning until the meter becomes unusable due to low battery.
10. A failed control solution does NOT lock the user out of the meter.
11. Beeps that are not disabled when ‘BEEP’ is set to OFF: The ‘quick triple beep’ warning for HI or LO errors and Error codes E0 to E4.

Appendix

12. The Meter responses to the pressing and the holding of keys:

SEARCH key

- The Meter responds immediately after the SEARCH key is pressed.
- In cases where the SEARCH key moves forward through a series of stored test result screens or increments a value, hold down the SEARCH key to speed up screen change process.

MODE key

- When the MODE key is pressed < 1.5 seconds to advance to the next function, the meter advances to next screen immediately when key pressed.
- While meter is in sleep mode (OFF), pressing the MODE button < 1.5 seconds wakes up the meter and enters data review mode.

- While meter is in sleep mode (OFF), pressing the MODE button > 3.0 seconds wakes up the meter and enters setup mode.
- While meter is awake (ON), pressing the MODE button > 1.5 seconds manually turns off the meter (sleep mode).
- While meter is in DATA REVIEW, pressing the MODE < 1.5 seconds puts into “Avg” screen of the next user.

13. With No Activity, Time-out will occur in
    1 Minute for all screens
    4 Minutes during analysis
    2 Minutes after the completion of analysis
    5 Minutes when upload connector inserted

Appendix

Warranty

Subject to the exclusions and upon the conditions specified below, Nova Biomedical or the authorized Nova Biomedical distributor warrants that he will correct free of all charges including labor, either by repair, or at his election, by replacement, any part of an instrument which fails within one (1) year from date of shipment because of defective material or workmanship. This warranty does not include normal wear from use and excludes: (A) Service or parts required for repair of damage caused by accident, neglect, misuse, altering the Nova equipment, unfavorable environmental conditions, electric current fluctuations, work performed by any party other than an authorized Nova representative or any force of nature; (B) Work which, in the sole and exclusive opinion of Nova, is impractical to perform because of location, alterations in the Nova equipment or connection of the Nova equipment to any other device; (C) Specification changes; (D) Service required to parts in the system contacted or otherwise affected by expendables or reagents not manufactured by Nova which cause shortened life, erratic behavior, damage or poor analytical performance; (E) Service required because of problems, which, in the sole and exclusive opinion of Nova, have been caused by any unauthorized third party; or (F) Instrument refurbishing for cosmetic

purposes. All parts replaced under the original warranty will be warranted only until the end of the original instrument warranty. All requests for warranty replacement must be received by Nova or their authorized distributor within thirty (30) days after the component failure. Nova Biomedical reserves the right to change, alter, modify or improve any of its instruments without any obligation to make corresponding changes to any instrument previously sold or shipped. All service will be rendered during Nova's principal hours of operation. Contact Nova for specific information.

The following exceptions apply:

- Consumable items, including the test strips and quality control solutions are warranted to be free of defects at time of initial use. The item must be placed into service prior to the expiration date printed on the packaging. All defects must be promptly reported to Nova Biomedical in writing.
- Freight is paid by the customer.

This warranty is invalid under the following conditions:

1. The date printed on the package label has been exceeded.
2. Non-Nova Biomedical reagents or controls are used, as follows: Nova Biomedical will not be responsible for any warranty on Lactate

Plus Meter if used in conjunction with and are adversely affected by reagents, controls, or other material not manufactured by Nova but which contact or affect such parts. Reagent or quality control solution formulations not manufactured by Nova Biomedical may contain acids, concentrated salt solutions, and artificial preservatives that have been shown to cause problems such as erratic analytical results or inaccurate meter performance.

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WARRANTIES, OF MERCHANTABILITY OR OTHERWISE, EXPRESSED OR IMPLIED IN FACT BY LAW AND STATE OUR ENTIRE AND EXCLUSIVE LIABILITY AND BUYER'S EXCLUSIVE REMEDY FOR ANY CLAIM OF DAMAGES IN CONNECTION WITH THE SALE OR FURNISHING OF GOODS OR PARTS, THEIR DESIGN, SUITABILITY FOR USE, INSTALLATION OR OPERATION. NOVA BIOMEDICAL WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, AND OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE CONTRACT PRICE FOR THE GOODS FOR WHICH THE LIABILITY IS CLAIMED.

LACTATE PLUS

Nova Biomedical
200 Prospect Street
Waltham, MA 02454-9141
U.S.A.

Telephone: 1-800-350-5024
1-781-894-0800
Fax: 1-781-894-5915
Web: www.novalactate.com

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